Randomized Controlled Trial of HIV Counseling with Rapid and Standard HIV Tests (RESPECT-2): *Preliminary results*

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LONG BEACH
RESPECT-2
NEWARK DENVER
CDC

RESPECT-2 Study Group

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Background

- STD clinics important providers of HIV CTR services.

- Project RESPECT: HIV testing with 2 brief (~20 minute) prevention counseling sessions more effective at preventing STDs than HIV testing with information alone.

- Influenced policy and practice of prevention counseling in US.

- BUT, low return rates for HIV test result and 2nd counseling session.

Background – Rapid HIV tests

- Enable preliminary HIV test result to be available within 30 minutes

- Negative results do not require confirmation

- Much higher proportion of clients receive their HIV result than with standard HIV tests

- Efficacy of completing prevention counseling in 1 visit compared to 2 visits unknown.

Objective

To compare rapid HIV testing and all counseling in 1 visit with standard HIV testing and 2 counseling sessions a week apart for efficacy at preventing STDs in STD clinic patients.

Methods

- Randomized Controlled Trial in 3 STD clinics

- Randomized:

  - Rapid or standard HIV test at enrollment

  - "Booster" (relapse prevention) counseling or no booster at 6 months

- Follow-up at 3, 6, 9, and 12 months

- Intention-to-treat analysis

Eligibility

- HIV-negative clients attending STD clinic for an STD examination

- Age: 15 - 39 yrs (18 - 39 yrs Newark)

- Required to consent, speak English, be available for 1 year follow-up, and have had sex in the past 3 months

- Enrollment: February 1999 - December 2000

Counseling Interventions

- Based on Project RESPECT / CDC model

- 2 sessions of ~20 minutes each at baseline

- HIV result given at start of 2nd session

- Approach and content similar in both groups

- Timing of the 2nd session:
  Rapid test - Same visit (after STD exam)
  Standard test - 1 week later

- Reminder letter and calls to maximize return for 2nd session (standard test group)

Outcome Measurement

STD

- Baseline and every 3 months: gonorrhea and *Chlamydia* (NAATs of urine), and *Trichomonas* (culture vaginal swab F, urine sediment M)

- Baseline and 12-months: HIV and syphilis

Behavioral

- Audio Computer-Assisted Self Interview (ACASI) at baseline and every 3 months

Enrollment and Randomization

Screened 9453

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Eligible 7554 (80%)

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Enrolled 3338 (44%) → Excluded 45 (1%) (35 HIV+)

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Participants 3293

Standard Test 1648 (50%)

Rapid Test 1645 (50%)

No Booster 1652 (50%)

Booster 1641 (50%)

Participant Demographics
(n = 3293)

- **Sex:** 46 % female

- **Race / ethnicity:** 51 % African-American
  22 % White
  18 % Hispanic
  9 % Other

- **Median / mean age:** Females 23 / 25 yrs;
  Males 25 / 26 yrs

- **Site:** Denver 38%, Long Beach 29%,
  Newark 33%

Baseline Risk Characteristics by HIV Test Type

Characteristic	Standard (n = 1648)	Rapid (n = 1645)
>1 partner last 3 mo	54 %	55 %
New partner last 3 mo	66 %	69 % (72 %)
MSM last 3 mo (of M)	9 %	10 %
STD at baseline	24 % (22 %)	26 % (27 %)

Completion of Baseline Counseling and follow-up by HIV Test Type

- Completed counseling (%)

  Standard   72
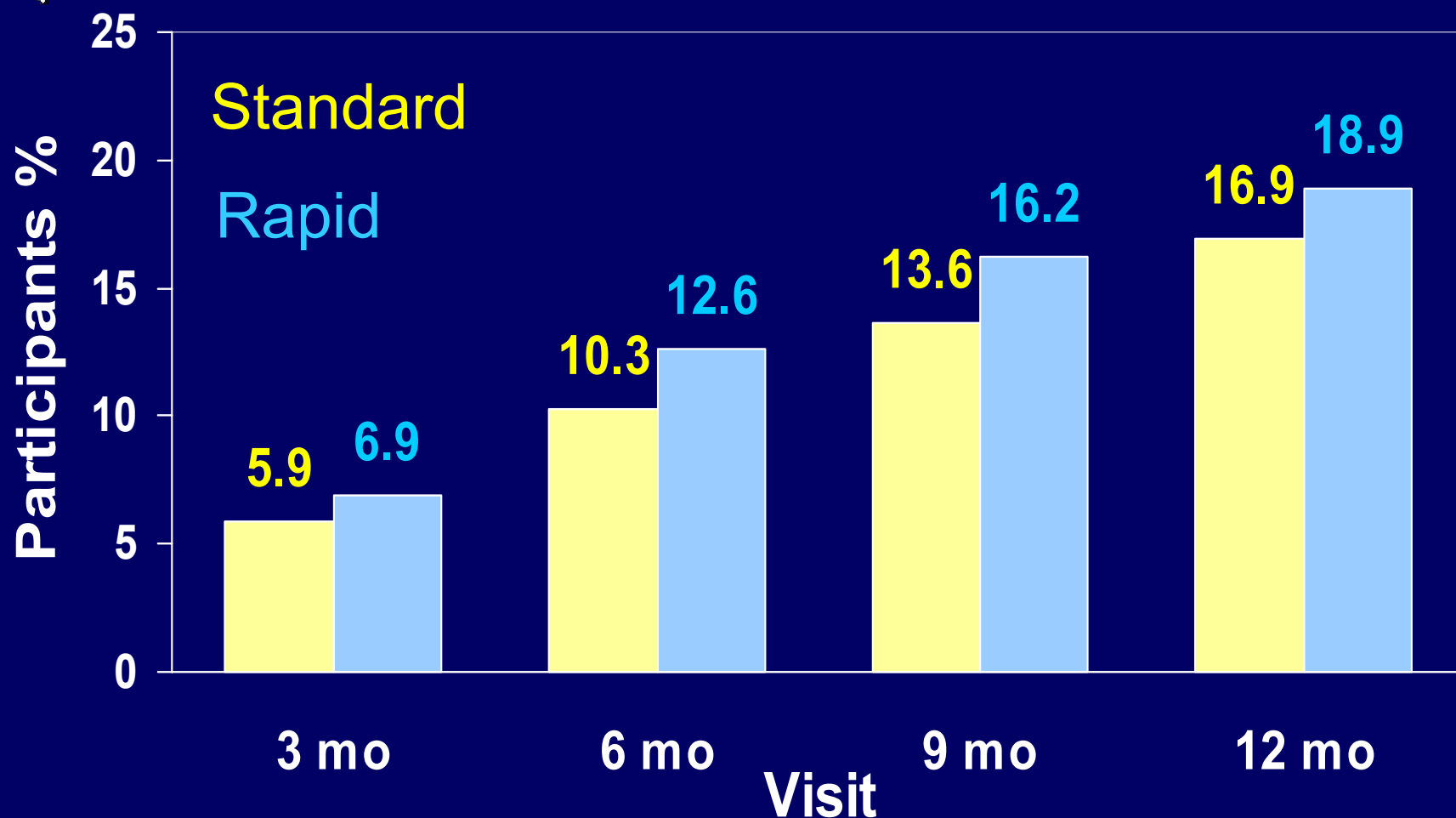
  Rapid   99

- Follow-up (% at 3, 6, 9, and 12 months)

  Standard   71 – 71 – 73 -- 73

  Rapid   72 – 72 – 71 -- 72

Cumulative Incidence of One or More STDs During Follow-up by HIV Test Type

Cumulative Incidence of One or More STDs During Follow-up
Rapid Test Group vs. Standard Test Group

Up to…	Risk Ratio (95% CI)	P-value
3 mo visit	1.17 (0.90-1.52)	0.25
6 mo visit	1.23 (1.01-1.49)	0.04
9 mo visit	1.19 (1.01-1.40)	0.04
12 mo visit	1.12 (0.97-1.30)	0.13

Relative Risk of STDs During Follow-up: Rapid Test Group Compared to Standard Test Group by Site

Up to…	Denver Risk Ratio (95% CI)	Long Beach Risk Ratio (95% CI)	Newark Risk Ratio (95% CI)
no visit	1.28 (0.84-1.97)	1.00 (0.57-1.76)	1.16 (0.77-1.75)
no visit	1.25 (0.92-1.69)	0.93 (0.60-1.43)	1.39* (1.03-1.8)
no visit	1.25 (0.97-1.61)	0.95 (0.65-1.37)	1.28 (0.98-1.67)
mo visit	1.13 (0.97-1.42)	0.96 (0.69-1.33)	1.21 (0.96-1.53)

Conclusion

- Results preliminary

- Substantially more patients received their HIV test result using a rapid HIV test than a standard HIV test.

- Overall standard 2-visit counseling was associated with fewer new STDs.

- Differences in STD rates between groups decreased over time.

Please visit the RESPECT-2 website:

www.cdc.gov/hiv/projects/respect-2